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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,902

08/10/2005

Kevin Jeffrey Barnham

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EXAMINER

SEAMAN, D MARGARET M

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

04/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,902	Applicant(s) BARNHAM ET AL.	
	Examiner D. Margaret Seaman	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 30-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/26/08&12/11/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application was filed 8/10/2005 and is a 371 of PCT/AU03/00914 (7/16/2003) which claims priority to AU 2002950217 (7/16/2002). Claims 1-29 have been canceled. Claims 30-35 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 30-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while maybe enabling for making salts of the claimed compounds, does not reasonably provide enablement for making solvates and hydrates of the claimed compounds. The specification does not enable any person skilled in the art of synthetic organic chemistry to make the invention commensurate in scope with these claims.

“The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of guidance or direction presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims”, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ

546. In the present case, the important factors leading to a conclusion of undue experimentation are c) the absence of any working example of a formed solvate or hydrate, the lack of predictability in the art, and the broad scope of the claims. There are no working examples of any hydrate or solvate formed. The claims are drawn to solvates and hydrates, yet the numerous examples presented all fail to produce a single hydrate or solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However...there is no evidence that such compounds exist...the examples of the '881 patent do not produce the postulated compounds...there is ... no evidence that such compounds even exist." The same circumstances appear to be true here. There is no evidence that solvates or hydrates of the instantly claimed compounds actually exist; if they did, they would have been formed. Hence, applicants must show that solvates and hydrates can be made, or limit the claims accordingly. G) The state of the art is that it is not predictable whether solvates or hydrates will form or what their composition will be. In the language of the physical chemist, a solvate of an organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Application, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and not part of the organic host molecule is left out or replaced. In the first paragraph on page

365, West says, "it is not usually possible to predict whether solid solution will form, or if they do form, what is their compositional extent". Thus, in the absence of experimentation, one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two or a half of a molecule of solvent added per molecule of host. In the same paragraph on page 365, west explains that it is possible to make meta--stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate. H) The breadth of the claims includes all of the hundreds of thousands of compounds of formula (I) as well as the presently unknown list of solvents embraced by the term "solvate" and all the possibilities for hydrates such as $\frac{1}{2}$ hydrate, 3 hydrate and $\frac{3}{4}$ hydrate. Thus, the scope is broad.

3. Claims 30-31 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds wherein R₃ and R' are H, does not reasonably provide enablement for compounds wherein R₃ and R' are substituted heterocycl. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

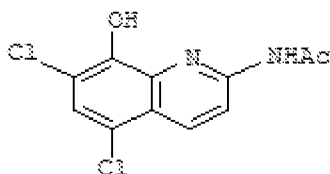
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 30-31 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Carissimi (US Patent 3682927), Zouhiri, Kacens and Vaidya.

Carissimi teaches compounds such as

IT 22275-37-2P
RL: SPN (Synthetic preparation); PREP (Preparation)
(preparation of)
RN 22275-37-2 CA
CN Acetamide, N-(5,7-dichloro-8-hydroxy-2-quinolinyl) -



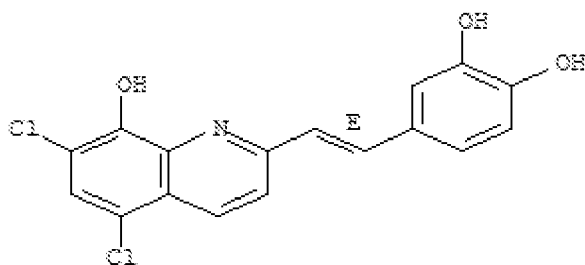
that anticipate the

instant claims. Zouhiri teaches compounds such as

Art Unit: 1625

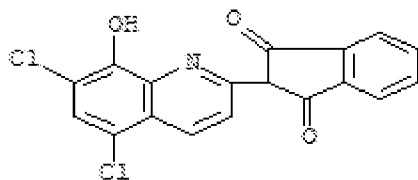
IT 266689-98-9P
 RL: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); SPW (Synthetic preparation); BIOL (Biological study); PREP (Preparation)
 (prepn, structure-activity relationships and binding mode of styrylquinolines as anti-AIDS agents)
 RN 266689-98-9 CA
 CN 1,2-Benzenediol, 4-[(1E)-2-(5,7-dichloro-8-hydroxy-2-quinolinyl)ethenyl]- (CA INDEX NAME)

Double bond geometry as shown.



that anticipate the instant claims. Kacens teaches compounds such as

IT 40619-43-0P
 RL: SPW (Synthetic preparation); PREP (Preparation)
 (preparation of)
 RN 40619-43-0 CA
 CN 1H-Indene-1,3(2H)-dione, 2-(5,7-dichloro-8-hydroxy-2-quinolinyl)- (INDEX NAME)

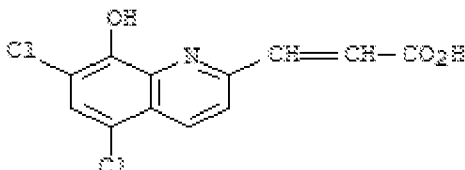


that

anticipate the instant claims. Vaidya teaches compounds such as

Art Unit: 1625

IT 24018-03-SP, 2-Quinolineacrylic acid, 5,7-dichloro-8-hydroxy-
RL: PREP (Preparation)
(preparation of)
RN 24018-03-5 CA
CN 2-Quinolineacrylic acid, 5,7-dichloro-8-hydroxy- (7CI, 8CI) (CA INDEX
NAME)



that anticipate the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carissimi. Carissimi teaches compounds such as shown above that differ from the instantly claimed compounds by the R2 moiety being -CH₂-N-Et₂ when the compounds instantly claimed have R2 being -CH₂-N-Me₂ or -CH₂-N(H)-Et.

It would have been obvious to one of ordinary skill in the art at the time of the invention to change the diethyl for monoethyl or dimethyl with the reasonable expectation of getting compounds having the same or similar activity. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Margaret Seaman/
Primary Examiner, Art Unit 1625